K060210

FEB 10 2006

**510(K) Summary**

This 510(K) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87(h)

**Company Identification:**

Maxant Technologies, Inc.
7540 Caldwell Avenue
Niles, Illinois 60714
Phone 847 588 2280
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**Registration Number:** 1419703

**Principal contact:**

Donald P. DeVale
Vice President -- Engineering
847 588 2280 extension 231

**Trade name and common name of device:** MEDIPORT a medical grade computer system, with a Windows XP Pro operating system, to be used as a platform for PACS software systems digital imaging.

**Device Classification:** The device is classified a Class II device, 90- LLZ under Title 21 of the Code of Federal Regulations (CFR) 892.2050, Picture archiving and communications systems.

**Device Description:** The MEDIPORT is a high performance medical grade computer with DICOM calibrated monitors that may be used as a platform for PACS software. It is designed for use in all Hospital environments (OR, ER etc.) as well as Physicians' Offices and Clinical Laboratories. It may also be used to access patient records or perform other functions that may be required.

**Intended Use** To provide an alternate technical solution for the display of medical images by providing a stable medical device qualified platform to host a PACS environment and by mounting in the same configuration as medical illuminators, thereby maintaining the same work flow and image availability provided by an illuminator.

**Substantially equivalent predicate devices**

Since the MEDIPORT is an assemblage of components and we are only providing a hardware system to act as a host for PACS software, we will list a relatively large number of equivalents in order to be sure of covering all.

a. Konica Minolta Medical Graphic, Inc. product REGIUS RS-1000. **K051521 Paragraph** 11 shows its hardware as Computer "Off the shelf"

| | MEDIPORT | REGIUS RS-1000 |
|---|---|---|
| CPU | Celeron D (Pentium 4 family) | Pentium 4 |
| Bus | PCI, PCI Express | PCI |
| Ram | Up to 4 GB | 1024MB |
| Hard drive | 40GB | 40GB |
| Floppy drive | None | 3.5" |
| CD | CD/DVD Rom | CD-ROM |
| | Keyboard | Keyboard |
| | Mouse | Mouse |
| Operating system | Embedded Windows XP-Pro | Windows XP |
| Ethernet | 10/100/1000T | LAN |
| Image Display | 1.3MP 19" Color | 1MP 16" Color |

Maxant is of the opinion that the MEDIPORT does not introduce any new potential safety risks and as a qualified medical device under UL60601-1 is superior in this regard and is substantially equivalent to and performs as well as this predicate device. This device in not qualified for use for mammographic purposes.

b. Siemens AG, Medical Solutions - **K052461**

Device Description
"The system is a "hardware independent" solution to be distributed either as software on or combined with common IT hardware which must comply to predefined minimum hardware requirements"

Technological Characteristics
"or as a complete radiology solution consisting of common IT hardware and pre-installed software."
"The workplaces are based on Windows XP. . . "

Maxant is of the opinion that the MEDIPORT does not introduce any new potential safety risks and as a qualified medical device under UL60601-1 is superior in this regard and is substantially equivalent to and performs as well as this predicate device. This device in not qualified for use for mammographic purposes.

c. Phillips Orthopaedic Applications - **K042867**

System Description
"The Phillips Orthopaedic Application software runs "off the shelf" standard PC components using a Microsoft Operating System."

Intended Use:
"The software packages are designed to run on standard PC hardware ("off the shelf" standard computer components) . . "

Maxant is of the opinion that the MEDIPORT does not introduce any new potential safety risks and as a qualified medical device under UL60601-1 is superior in this regard and is substantially equivalent to and performs as well as this predicate device. This device in not qualified for use for mammographic purposes.

d. Totoku K050485, **K050619**
20.8" Gray scale or color 3MP monitor with DICOM calibration.

Maxant is of the opinion that the MEDIPORT does not introduce any new potential safety risks and is substantially equivalent to and performs as well as this predicate device.

Since our customers can select the monitor that is used in our system based on their preference, Totoku monitors may be used or any monitor that meets UL60601-1 and has 510(K) clearance. Please note that these monitors are purchased as "open frame" and mounted in the MEDIPORT enclosure using power supplies that meet medical standards. This device in not qualified for use for mammographic purposes.

e. BarcoView **K052276**
20.1" Gray scale 2MP monitor with DICOM calibration.

Maxant is of the opinion that the MEDIPORT does not introduce any new potential safety risks and is substantially equivalent to and performs as well as this predicate device.
Since our customers can select the monitor that is used in our system based on their preference, BarcoView monitors may be used or any monitor that meets UL60601-1 and has 510(K)

clearance. Please note that these monitors are purchased as "open frame" and mounted in the MEDIPORT enclosure using power supplies that meet medical standards. This device in not qualified for use for mammographic purposes.

**Applicable mandatory and voluntary standards**

DICOM (Digital Imaging and Communications in Medicine) Developed by the American College of Radiology and the National Electrical Manufacturers Association.

UL60601-1 as a class 1 medical device

UL60601-1-2 emissions (FCC class B) and immunity standards

I certify that the MEDIPORT conforms to the above-mentioned specifications and standards. The UL reports are available for review. The monitors that are included in this system are factory calibrated each with it's own DICOM Gamma Correction Curve. This built in Look Up Table (LUT) assures accurate reproduction of the image from the monitor regardless of the luminance set point. The monitor will display 256 distinct shades of gray from a pallet of 1024 shades stored on the internal graphics driver card.

While UL544 and UL187 are CDRH recognized standards, it should be noted that UL60601-1 (or EN60601-1) has replaced UL187 and incorporates what is also in UL544.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2006

MAXANT Technologies, Inc.
% Mr. Glenn Luchen
Staff Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747

Re: K060210
Trade/Device Name: MEDIPORT
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 24, 2006
Received: January 27, 2006

Dear Mr. Luchen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K066210

**Device Name:** MEDIPORT

**Indications for Use:**

The MEDIPORT is a medical grade device to be used as a platform for PACS software or DICOM viewer software. It is intended for use in all Hospital environments (OR, ER etc.) as well as Physicians' Offices and Clinical Laboratories.

In light of the fact that MEDIPORT is a high performance computer it may also be used to access patient records or perform other functions that may be required.

This device in not qualified or intended for use for mammographic purposes.

| Prescription Use | X | ~~AND~~ / OR | Over-The-Counter-Use |
|---|---|---|---|
| (Part 21 CFR 801 Subpart D) | | | (Part 21 CFR 801 Subpart C) |

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
[illegible]ardiological Devices
[illegible] Number K060210